



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Guenther ADOLF et al) Art Unit: To be assigned
U.S. Appln. No. : 10/645,215) Examiner: To be assigned
Confirmation No. : To be assigned
U.S. Filing Date : August 21, 2003
Title of Invention : Compositions and methods for treating cancer using cytotoxic CD44
antibody immunoconjugates and chemotherapeutic agents
Attny. Docket No.: 1/1383

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

November 20, 2003

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§1.56 and 1.97, as more specifically described hereinbelow.

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

☐ A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

☐ 1.97(e).

☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

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☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,

Susan K. Pocchiari

Susan K. Pocchiari
Attorney for Applicant(s)
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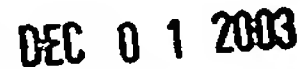
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Approved for use through 07/31/2006. OMB 0651-0031

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Sheet 1 of 3

Application Number	10/645,215
Filing Date	August 21, 2003
First Named Inventor	Guenther ADOLF et al
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	1/1383

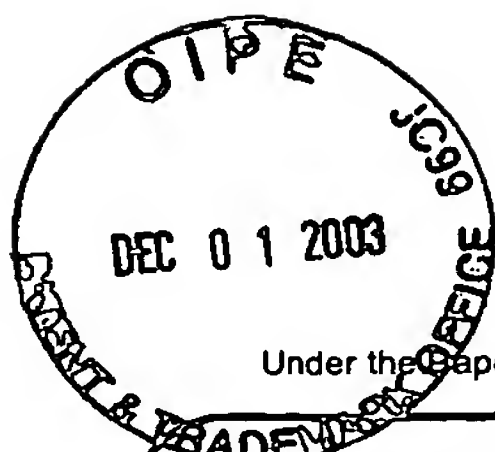
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known).				
		WO 01/24763	04/12/2001	IMMUNOGEN, INC.		
		WO 98/22508	05/28/1998	Boehringer Ingelheim International GmbH		
		WO 01/00244	01/04/2001	GENENTECH, INC.		
		WO 97/21104	06/12/1997	Boehringer Ingelheim International GmbH		
		WO 98/39034	09/11/1998	Boehringer Ingelheim International GmbH		

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

3

of

3

Complete if Known

Application Number

10/645,215

Filing Date

August 21, 2003

First Named Inventor

Guenther ADOLF et al

Art Unit

To be assigned

Examiner Name

To be assigned

Attorney Docket Number

1/1383

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		DIANNE L. NEWTON ET AL; Anti-tumor ribonuclease, combined with or conjugated to monoclonal antibody MRK16, overcomes multidrug resistance to vincristine in vitro and in vivo; International Journal of Oncology Vol. 8 page 1095-1104, 1996; BCDP, SAIC, Frederick MD 21702	
		K. FOWERS; Targeting of HPMA Copolymer-Drug Conjugates to A2780/AD Ovarian Cancer Cells Using Anti-P-Glycoprotein Antibodies of Fragments; Int'l Symp. Control. Rel. Bioact. Mater. 26 Vol. 7 page 527-528, 1999; Department of Bioengineering University of Utah Salt Lake City, Utah 84112	
		WU MIN; Potent Deglycosylated Ricin a Chain Immunotoxins Specifically Killing of Xenotropic Murine Retrovirus - Infected Cells; Chinese Medical Journal Vol. 5 page 383-385, 1994; Department of Pathology, Tohoku University School of Medicine Sendai 980, Japan	
		ROM E. ELIAZ; Liposome-encapsulated Doxorubicin Targeted to CD44: A Strategy to Kill CD44 overexpressing Tumor Cells; Cancer Research Vol. 61 page 2592-2601 March 15, 2001; Dept. of Biopharmaceutical Sciences and Pharmaceutical Chemistry School of Pharmacy University of San Francisco CA. 94143-0446	
		K.H. HEIDER; Splice Variants of the Cell Surface Glycoprotein CD44 Associated with Metastatic Tumor Cells are Expressed in Normal Tissues of Humans and Cynomolgus Monkeys; European Journal of Cancer Vol. 31A page 2385-2391, 1995; Boehringer Ingelheim Research and Development, Vienna, Austria Department of Pathology	
		K.H. HEIDER; Characterization of a high-affinity monoclonal antibody specific for CD44v6 as candidate for immunotherapy of squamous cell carcinomas; Cancer Immunol Immunother Vol. 43 page 245-253, 1996; Boehringer Ingelheim Research and Development Bender & Co. GesmbH, Vienna Austria	
		RAVI V.J. CHARI; Immunoconjugates Containing Novel Maytansinoids Anticancer Drugs; Cancer Research Vol. 52 page 127-131 January 1, 1992; ImmunoGen Inc. Cambridge Mass. 02142	
		CHANGNIAN LIU ET AL; The development of antibody delivery systems to target cancer with highly potent maytansinoids; Exp. Opin. Invest. Drugs Vol. 6(2) page 169-172, 1997; Ashley Publications Ltd. ISSN 1354-3784	
		CHANGNIAN LIU; Eradication of large colon tumor xenografts by targeted delivery of maytansinoids; Proc. Natl. Acad. Sc. USA Vol. 93 page 8618-8623 August 1996; ImmunoGen Inc. 148 Sidney Street Cambridge MA 02139-4239	
		CLAUDE MONNERET ET AL; Ciblage de molecules antitumorales par les anticorps monoclonaux; Bull Cancer Vol. 87 (11) page 829-838, 2000; Institut Curie, 26 rue d'Ulm 75248 Paris Cedex 05	

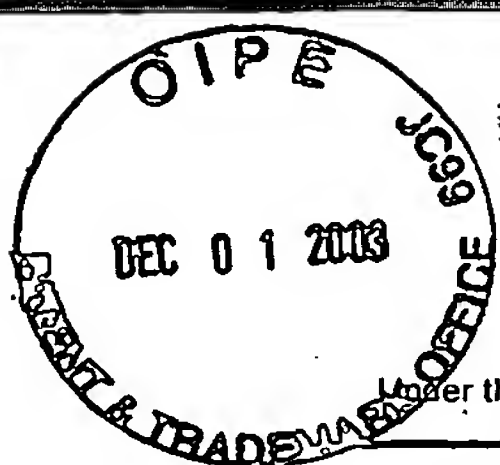
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/645,215
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				First Named Inventor	Guenther ADOLF, et al
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	2	of	3	Attorney Docket Number	1/1383

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
		C. LIU ET AL; Cure of large human colon cancer xenografts by a C242-Maytansinoid conjugate; April 24, 1996, Vol. 2 page 466-467; ImmunoGen Inc. Cambridge MA.		
		SUZANNE SMITH; Technology evaluation: C242-DM1, ImmunoGen Inc; Current Opinion in Molecular Therapeutics Vol.3(2) page 198-203 dated 2001; Pharma Press Ltd ISSN 1464-8431		
		MATTHEW J. SCHIBLER ET AL; Maytanise-resistant mutants of Chinese hamster ovary cells with an alteration in alpha-tubulin; Cell Biol. Vol 63 page 503-510 September 13, 1984; Division of Endocrinology, University of Texas Medical School P.O. 20708 Houston TX. 77225		
		RADHEY S. GUPTA; Cross-Resistance of Vinblastine- and Taxol-Resistant Mutants of Chinese Hamster Ovary Cells to Other Anticancer Drugs; Cancer Treatment Reports Vol. 69 No. 5 page 515-521 May 5, 1985; Dept. of Biochemistry McMaster Univ. Hamilton Ontario Canada		
		JOHN J. CORREIA; Effects of Antimitotic Agents on Tubulin-Nucleotide Interactions; Pharmac Ther. Vol. 52 page 127-147, 1991; Department of Biochemistry University of Mississippi Medical Center 2500 North Street Jackson, MS. 39216		
		ALLAN JORDAN ET AL; Tubulin as a Target for Anticancer Drugs: Agents which Interact with the Mitotic Spindle; Cancer Research Vol. 38 Page 259-296 dated 1998; Department of Chemistry Univ. of Manchester Inst. of Science and Tech. P.O. 88, Manchester M60 1OD, UK		
		JOEP W.G. STROOMER ET AL; Safety and Biodistribution of 99mTechnetium-labeled Anti-CD44v6 Monoclonal Antibody BIWA 1 in Head and Neck Cancer Patients; Clinical Cancer Research Vol. 6 page 3046-3055, August 2000; Dept of Otolaryngology/Head and Neck Surgery Nuclear Medicine Free University Hospital, Amsterdam, The Netherlands		
		European Search Report for European Counterpart EP 02018686 of the instant application. August 18, 2003.		

Examiner Signature		Date Considered	
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